IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	Confirmation No.: 3322
Joseph R. BYRUM *et al.*	Art Unit: 1633
Application No.: 09/199,129	Examiner: Janet L. EPPS FORD
Filed: November 24, 1998	Atty. Docket: 16517.140

Title: Nucleic Acid Molecules and Other Molecules Associated with Plants

APPELLANTS' SECOND AMENDED BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on August 31, 2005. An Appellants' Brief was filed on October 31, 2005, at which time the statutory fee for submitting an appeal brief was paid. An Appellants' Amended Brief was submitted on September 25, 2006. This Appellants' Second Amended Brief is submitted in response to the Office Communication mailed March 13, 2007, which alleged that the Brief filed September 25, 2006 was non-compliant with 37 C.F.R. § 41.37(c).

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellants identify the following judicial proceeding, which may have a bearing on the Board's decision in the present Appeal. On May 27, 2004, the Real Party in Interest in the above-captioned matter filed an appeal to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") from a decision by the Board in *In re Fisher.* (U.S. Appln. No. 09/619,643, BPAI Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465). The Federal Circuit's decision in *In re Fisher* may have a bearing on the Board's decision with regard to at least one of the grounds of rejection in the present appeal.

In addition, Appellants also identify the following additional Board decisions which may have a bearing on the instant appeal: U.S. Appln. No. 09/654,617, BPAI Appeal No. 2003-1744; U.S. Appln. No. 09/620,392, BPAI Appeal No. 2003-1746; U.S. Appln. No. 09/540,232, BPAI Appeal No. 2003-1137; U.S. Appln. No. 09/440,687, BPAI Appeal No. 2003-1504; U.S. Appln. No. 09/565,240, BPAI Appeal No. 2003-1135; U.S. Appln. No. 09/540,215, BPAI Appeal No. 2003-0996; U.S. Appln. No. 09/552,087, BPAI Appeal No. 2004-1772; and U.S. Appln. No. 09/206,040, BPAI Appeal No. 2002-0078.[1]

Appellants also identify the following pending appeals before the Board which may have a bearing on the instant appeal: U.S. Appln. No. 09/233,218, BPAI Appeal No. 2004-1725; U.S. Appln. No. 09/540,234, BPAI Appeal No. 2003-1073; U.S. Appln. No. 09/333,535, BPAI Appeal No. 2003-1939; U.S. Appln. No. 09/666,355, BPAI Appeal No. 2004-1034; U.S. Appln. No. 09/552,086, BPAI Appeal No. 2003-1074; U.S. Appln. No. 09/637,086, BPAI Appeal No.

[1] Copies of the Board's decision in Appeal No. 2002-2046, a copy of *In re Fisher*, and copies of the Board's decisions in the listed appeals were submitted with Appellants' Brief filed October 31, 2005. In the interest of efficiency, Appellants are not submitting additional copies herewith.

2004-1273; U.S. Appln. No. 09/540,235, BPAI Appeal No. 2004-1275; U.S. Appln. No. 09/553,094, BPAI Appeal No. 2004-1406; U.S. Appln. No. 09/267,199, BPAI Appeal No. 2004-2136; U.S. Appln. No. 09/521,640, BPAI Appeal No. 2004-1666; U.S. Appln. No. 09/371,146, BPAI Appeal No. 2004-1272; U.S. Appln. No. 09/421,106, BPAI Appeal No. 2004-1773; and U.S. Appln. No. 09/732,627, BPAI Appeal No. 2004-1480.[2]

3. Status of Claims

Claims 4-12 are pending. Claims 2, 3 and 13-17 were cancelled without prejudice to or disclaimer of the subject matter claimed therein in an amendment filed July 2, 2002. Claim 1 was cancelled without prejudice to or disclaimer of the underlying subject matter in an amendment filed January 26, 2005. Claims 4-12 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellants appeal all of the rejections of claims 4-12.

4. Status of Amendments

Appellants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of the Claimed Subject Matter

Independent Claim 4. The subject matter of independent claim 4 is directed to a transformed plant having a nucleic acid molecule which comprises: (a) an exogenous promoter region which functions in a plant cell to cause the production of an mRNA molecule; (b) a structural nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 and complement thereof; and (c) a 3' non-translated sequence that functions to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

[2] At the time Appellants filed the Appellants' Brief filed October 31, 2005, it had been requested that these appeals be suspended. Those appeals were subsequently suspended and were withdrawn from the Board of Patent Appeals

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Specification at page 12, lines 7-15; page 57, line 13 through page 62, line 13; page 19, line 11 through page 24, line 2; and page 62, lines 14-19.

Independent Claim 8. The subject matter of independent claim 8 is directed to a method of determining a level or pattern in a plant cell or plant tissue of a protein in a plant comprising: (a) incubating, under conditions permitting nucleic acid hybridization, a marker nucleic acid molecule which specifically hybridizes to a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 1 or complement thereof, with a complementary nucleic acid molecule obtained from the plant cell or plant tissue, where hybridization permits the detection of an mRNA for the protein; (b) permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue; and (c) detecting the level or pattern of said complementary nucleic acid, where the detection of said complementary nucleic acid is predictive of the level or pattern of said protein. *Specification* at page 15, lines 3-16; page 20, line 17 through page 22, line 12; page 33, line 19 through page 34, line 20.

6. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed in this Appeal are:

(a) pending claims 4-12 stand rejected under 35 U.S.C. § 101, for allegedly not being supported by a specific asserted utility or a well established utility;

(b) pending claims 4-12 stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility; and

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and Interferences. None of these appeals are currently pending.

(c) pending claims 4-12 stand rejected under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description.

A. Grouping of Claims

Claims 4-12 are pending in this application. All of the claims at issue do not stand or fall together. The separate patentability of claims 4-7 and 8-12 is addressed together in Sections 7.B.(1)(a) and 7.B.(1)(b) below. In addition, the separate patentability of claim 9, and the separate patentability of claim 10 are addressed in Sections 7.B(1)(c) and 7.B(1)(d), respectively.

7. Argument

A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility ... where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Appellants have met their part of the bargain – they have disclosed transformed plants and methods that, in their current form, provide at least one specific benefit to the public, for example, use of the transformed plants in a breeding program. This benefit is specific, and it is a "real world" or substantial benefit. Because the claimed plants and methods provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed plants and methods for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has likewise been met.

Furthermore, Appellants have provided an adequate description of the plants and methods that demonstrates Appellants' possession of the claimed invention. Each genus of nucleic acid

molecule in the claimed plants and methods, *e.g.*, transformed plants comprising the nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1, for example, has been described by the recitation of a common structural feature – the nucleotide sequence of SEQ ID NO: 1 – which distinguishes plants having molecules within the genus from plants having molecules outside of the genus. Because the specification demonstrates that Appellants have possession of (and have provided an adequate description of) the claimed plants and methods, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Claimed Plants and Methods Have Legal Utility

Pending claims 4-12 were erroneously rejected under 35 U.S.C. § 101 because the claimed invention was allegedly "not supported by either a specific and/or substantial utility or a well-established utility." Final Action at pages 2-6. According to the Final Action, the "specification does not disclose or provide any evidence that points to a specific or substantial biologically significant activity for nucleic acid comprising SEQ ID NO: 1, a plant comprising said nucleic acid, or a method of identifying an unknown protein, such that another non-asserted utility would be well-established." *Id.* at page 4.

The specification discloses that the claimed transgenic plants and methods can be used in breeding programs and expression assays. *See, e.g.*, Specification at page 18, lines 18-19, page 56, line 15 through page 75, line 10, and page 44, line 20 through page 48, line 21. The Examiner asserts "there is no art of record that discloses or provides any evidence that points to an activity for SEQ ID NO: 1 or its corresponding full length cDNA or the proteins that might be obtained using the full length cDNA to be obtained, such that another non-asserted utility would be well established." *Id.*

The Examiner further argues that "Applicants have not identified any practical benefit of either the claimed plant or methods since neither the specification as filed, nor any prior art teaches or provides any evidence that defines any beneficial biological activity for the nucleic acid that is transformed into the plant, or assayed for in the claimed methods." *Id.* at page 5.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966).

The Federal Circuit has recently reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, -- U.S.P.Q.2d -- (Fed. Cir. 2005) (citing *Brenner*, 383 U.S. at 534-35) (emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.*

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit discerned the kind of disclosure an application could contain to establish a specific and substantial utility. *Id.* First, the Court indicated that the specification disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public.*" *Id.* (emphasis original). Second, the specification should also disclose "a use which is not so vague as to be meaningless," that is that

the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

It is well-established that claims must be considered as a whole in determining compliance with § 101. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 U.S.P.Q. 1, 9 (1981). It is inappropriate to dissect claims and consider some elements while ignoring others. *Id.* Further, it is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983).

Appellants have asserted in the specification that the claimed transgenic plants and methods provide clear and immediate benefits, for example, use to follow a plant through a breeding program (*see, e.g.*, specification at page 18, lines 18-19, page 56, line 15 through page 75, line 10), and to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule (*see, e.g.*, specification at page 44, line 20 through page 48, line 21). Either of these utilities described alone is enough to satisfy Section 101. Because Appellants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Plants and Methods Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The specification describes multiple utilities for the present invention, including in breeding programs and in expression assays. Such uses provide a well-defined use that is not so vague as to be meaningless.

(a) Use of Transgenic Plants in Breeding Programs

For example, one of the utilities disclosed in the specification is use of the claimed transgenic plants in breeding programs (*see, e.g.*, specification at page 18, lines 18-19, page 56, line 15 through page 75, line 10). The Examiner rejects this asserted utility apparently because "neither the specification as filed, nor the prior art teaches or provides any evidence that defines any beneficial biological activity for the nucleic acid." Final Action at page 5. Contrary to the Examiner's position, the transformed plants having, *inter alia*, a structural nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:1 or complement thereof, have utility independent of whether a function is known for the nucleic acid sequence. The specification discloses methods for the preparation of the transgenic plants as well as use in breeding programs to produce plants having genes of interest. *See, e.g.*, specification at page 18, lines 18-19 and page 56, line 15 through page 75, line 10. The specification further describes that the nucleic acid sequences can be used as markers. *See, e.g.*, specification at page 48, line 22 through page 49, line 5. The skilled artisan would recognize that such transformed plants can be more easily followed through a breeding program by the detection of the nucleic acid molecule. These utilities are immediately apparent for the claimed plants and methods without the need for further research.

The Examiner argues that this utility is not specific or substantial, apparently because this utility is "directed to basic research that involves studying the properties of the claimed transformed plant." Final Action at page 4. The Examiner also argues that this utility is not "specific since the recited use can be generally applied to any plant transformed with any cDNA molecule or fragment thereof." *Id.* The use of the claimed transformed plants having a nucleic acid molecule comprising, *inter alia*, a structural nucleic acid molecule comprising a nucleic acid

sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof in plant breeding programs is not a use directed to "basic research." Rather, using the claimed transformed plants in a breeding program allows the breeder to readily track the transformed plant through the program by identifying progeny plants containing the nucleic acid molecule. Such a use is a well-defined utility. For example, progeny resulting from a cross between a claimed transformed plant having a desired background and a plant having a trait of interest to be introgressed into the transformed plant can be screened quickly for identification of the nucleic acid molecule. Such a plant allows for the high-throughput screening of progeny plants to obtain the desired commercial plant.

The asserted use of the claimed plants in breeding programs is not a "nebulous" or "obscure" expression of utility. The claimed transformed plants have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, for use in breeding programs. This benefit is immediately realized directly from the use of the claimed transformed plants, not from the use of other plants. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Methods for Determining a Level or Pattern in a Plant Cell or Plant Tissue of a Protein in a Plant

Uses for the claimed methods include detecting the presence or absence or level of expression of the sequence in a sample (*See e.g.*, specification at page 44, line 20 through page 48, line 21). The Examiner suggests that these uses are not legal utilities because "further experimentation would be required to identify the full length cDNA comprising SEQ ID NO: 1, isolate the protein encoded by the full length cDNA, and furthermore identify the biological activity of the encoded protein." Final Action, at page 6. This is not correct. Such methods can

be used, for example, to assay gene expression in plant cells treated with an herbicide to detect target genes for producing herbicide tolerant plants. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be detected using a claimed method is the nucleic acid sequence of SEQ ID NO: 1. Appellants have specifically disclosed that one use of the claimed method is to detect the level in a plant cell or plant tissue of a protein in a plant. Specification at page 44, line 20 through page 48, line 21. The Examiner denigrates that utility by asserting that it is not specific because it is generally applicable to any nucleic acid. Final Action at pages 4-5. This is not correct. The claimed methods using the nucleic acid molecules are particularly useful, for example, to detect the level in a plant cell or tissue of an mRNA corresponding to SEQ ID NO: 1. *See, e.g.*, specification at page 44, line 20 through page 48, line 21.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *e.g.,* monitoring gene expression or in a breeding program. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result ..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls.

That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed plants and methods. The claimed methods and plants provide a particularly appropriate and demonstrably useful starting point for example, to screen for compounds with herbicidal activity. A random nucleic acid molecule does not provide an equally good starting point for such an assay as a random nucleic acid molecule would not necessarily correlate to an expressed gene. Furthermore, even if a random nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed plants and methods. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

(c) Methods for Determining a Level or Pattern in a Plant Cell or Tissue of a Protein in a Plant using *In Situ* Hybridization

The specification discloses additional specific and substantial uses of the methods, for example for use in *in situ* hybridizations (*See, e.g.*, Specification at page 45, line 10 through page 47, line 11 and Claim 9). *In situ* hybridization is a highly sensitive technique that can detect as few as 5-10 copies of an RNA sequence per cell and generally involves tissue preparation, hybridization, and washing conditions, and can be used, *inter alia*, to map chromosomal locations of genes, and as diagnostic tools. *See, e.g.*, Specification at page 45, line 10 through page 47, line 11. *In situ* hybridization can be used in a number of uses, for example

to determine the spatial population or the steady-state levels of RNA accumulation in a tissue. One of the most common uses of *in situ* hybridization is to localize specific RNA sequences in cells, which is useful for gene mapping, following chromosomes in hybrid lines or detecting chromosomes with translocations, transversions, or deletions. As such, methods for determining the level or pattern in a plant cell or plant tissue of a protein using *in situ* hybridization provides a useful tool for studying cellular processes.

Many of the disclosed utilities in this case, including *in situ* hybridization, are directly analogous to the utilities of a microscope, *i.e.*, the claimed methods employing the recited nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because "[w]ithout identifying the biological activity of the encoded protein, the skilled artisan would not be able to recognize the real-world context of use of the" claimed methods. Final Action, at page 6. However, the fact that, *e.g.*, a new and non-obvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed methods to determine the level or pattern of a protein is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the

gas.[3] Likewise, the claimed methods have utility even if the absence of a particular molecule is detected. Indeed, the absence of the corresponding molecule usefully demonstrates that the nucleic acid molecule is not expressed in a given cell or tissue.

(d) Methods for Determining a Level or Pattern in a Plant Cell or Tissue of a Protein in a Plant using Tissue Printing

The specification also discloses that the methods can be used to detect the level or pattern of a protein using tissue printing (*See,* Claim 10). Tissue printing provides a convenient method to simultaneously screen on a single membrane many tissue sections from different plants or different developmental stages. Tissue printing procedures utilize various films designed to immobilize proteins and nucleic acids. Briefly, a freshly cut section of a plant tissue or organ is pressed gently onto nitrocellulose paper, nylon membrane, or polyvinylidene difluoride membrane. Such methods can be used to visualize RNA accumulation in tissues and organs and during different developmental stages. The specification discloses that tissue printing can be used for the histochemical localization of various plant enzymes and nucleic acids. *See, e.g.* Specification at page 47, line 12 through page 48, line 17.

Such utility, as are many of the disclosed utilities, is also directly analogous to the utilities of a microscope, *i.e.*, the claimed methods employing the recited nucleic acid molecules in tissue printing may be used to spatially and temporally localize proteins and nucleic acid molecules within a sample, cell, or organism.

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[3] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed plants and methods could not be so used. Accordingly, the assertion of this utility in a breeding program or in expression assays satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Transgenic Plants and Methods Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses for the claimed plants or the claimed methods are legally insufficient because they are not "substantial" utilities. Final Action at pages 2-6. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[4]

There can be no question that one skilled in the art can use the claimed transgenic plants and methods in a manner which provides an immediate benefit to the public, for example to easily identify progeny of interest in a breeding program. The detection of transgenic plants provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to more efficiently allocate resources to progeny plants having a given genetic profile. This information

[4] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[5] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Appellants have explicitly identified specific and substantial utilities, not only in the specification, but in Appellants' responses. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner

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[5] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

has provided no evidence that the claimed plants and methods will not work for the asserted utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Appellants contend that the claimed plants and methods are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of pending claims 4-12 under 35 U.S.C. §101 is improper and should be reversed.

C. The Claimed Plants and Methods Are Enabled by the Specification

The enablement of the claimed transgenic plants and methods has been challenged. Claims 4-12 have been erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 7. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides an Adequate Written Description of the Claimed Invention

The adequacy of the written description of the claimed invention of claims 4-12 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) ... had possession of the claimed invention." Final Action at page 7. The Examiner contends that the rejection has been maintained "for the reasons of record set forth in the Examiner's Answer mailed 10/23/2002." Final Action at page 7. The Examiner rejects the claims on the basis of "the breadth of the claims are directed to plants transformed with nucleic acids encompassing full length gene sequences (i.e. gene sequences yet to be discovered) and cDNAs comprising SEQ ID NO: 1, sequences that hybridize to SEQ ID NO: 1, and methods which utilize such sequences." Final Action at page 8. However, the specification demonstrates to one skilled in the art that Appellants were in possession of the claimed invention containing the genera of nucleic acid molecules.

(1) The Specification Reflects Appellants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584.

A person of ordinary skill in the art would, after reading the present specification, understand that Appellants had possession of transgenic plants and methods employing nucleic acid molecules comprising or specifically hybridizing to a nucleic acid sequence of SEQ ID NO: 1. Appellants have provided the nucleotide sequence required by the claims, *e.g.*, SEQ ID NO: 1. Accordingly, Appellants have demonstrated possession of the claimed invention.

The fact that the claims at issue are intended to include molecules that encode the recited enzymes or fragments of the recited nucleic acid sequence, the recited sequence joined with additional sequences, related sequences or complements of the recited sequence, does not mean that Appellants were any less in possession of the nucleic acid molecules.[6] It is well-established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (BPAI 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence recited by the claims (*e.g.* SEQ ID NO: 1). For example, the specification describes the transformation of plants with vectors having the claimed nucleic acid molecules (*See, e.g.*, specification at page 66, line 12 through page 75, line 10) as well as methods for determining gene expression (*See, e.g.*, specification at page 15, lines 3-16 and page 47, line 8 through page 50, line 15). Moreover, the

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[6] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

present application describes more than just the nucleotide sequence used in the claims (SEQ ID NO: 1). For example, it describes vectors comprising the nucleic acid molecules, Specification at page 56, line 15 through page 66, line 11, and describes how to make the nucleotide sequences and the libraries from which they were originally purified. *See* specification at page 1, line 16 through page 4, line 23, and Examples 1-2.

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). A complete structure of every species within a chemical genus is not required. *See, e.g., Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

The Examiner asserts that the claimed invention covers "gene sequences yet to be discovered", and accordingly Appellants have allegedly not adequately disclosed the genera of nucleic acid molecules. Final Action at page 8. As such, the Examiner appears to require that each nucleic acid molecule within the genera must be described by its complete structure. This requirement is totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that

distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Appellants have satisfied that test for written description.

In particular, Appellants have disclosed common structural features of the nucleic acid molecule recited in claim 4, for example the nucleotide sequence of SEQ ID NO: 1. The respective common structural feature (the nucleotide sequence of SEQ ID NO: 1) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Similarly, if a nucleic acid molecule specifically hybridizes to the nucleic acid sequence of SEQ ID NO: 1, then it is a member of the genus of nucleic acid molecules recited in claim 8. If the nucleic acid molecule does not specifically hybridize, then it is not a member of that genus.

Thus, claims 4-12 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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CLAIMS APPENDIX

Claim 4. A transformed plant having a nucleic acid molecule which comprises:

(a) an exogenous promoter region which functions in a plant cell to cause the production of an mRNA molecule;

(b) a structural nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof; and

(c) a 3' non-translated sequence that functions in said plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.

Claim 5. The transformed plant according to claim 4, wherein said structural nucleic acid molecule is a complement of the nucleic acid sequence of SEQ ID NO: 1.

Claim 6. The transformed plant according to claim 5, wherein said plant is soybean or maize.

Claim 7. The transformed plant according to claim 5, wherein said plant is soybean.

Claim 8. A method for determining a level or pattern in a plant cell or plant tissue of a protein in a plant comprising:

(a) incubating, under conditions permitting nucleic acid hybridization, a marker nucleic acid molecule, said marker nucleic acid molecule selected from the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid molecule having the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 or complement thereof, with a complementary nucleic acid molecule obtained from said plant cell or plant tissue, wherein nucleic acid

hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue permits the detection of an mRNA for said protein;

(b) permitting hybridization between said marker nucleic acid molecule and said complementary nucleic acid molecule obtained from said plant cell or plant tissue; and

(c) detecting the level or pattern of said complementary nucleic acid, wherein the detection of said complementary nucleic acid is predictive of the level or pattern of said protein.

Claim 9. The method of claim 8, wherein said level or pattern is detected by *in situ* hybridization.

Claim 10. The method of claim 8, wherein said level or pattern is detected by tissue printing.

Claim 11. The method of claim 8, wherein said plant is maize or soybean.

Claim 12. The method of claim 11, wherein said plant is soybean.

EVIDENCE APPENDIX

No New Evidence

RELATED PROCEEDINGS APPENDIX

1. *In re Fisher*, 412 F.3d 1365 (Fed. Cir. 2005);
2. U.S. Appln. No. 09/619,643, BPAI Appeal No. 2002-2046;
3. U.S. Appln. No. 09/654,617, BPAI Appeal No. 2003-1744;
4. U.S. Appln. No. 09/620,392, BPAI Appeal No. 2003-1746;
5. U.S. Appln. No. 09/540,232, BPAI Appeal No. 2003-1137;
6. U.S. Appln. No. 09/440,687, BPAI Appeal No. 2003-1504;
7. U.S. Appln. No. 09/565,240, BPAI Appeal No. 2003-1135;
8. U.S. Appln. No. 09/540,215, BPAI Appeal No. 2003-0996;
9. U.S. Appln. No. 09/552,087, BPAI Appeal No. 2004-1772; and
10. U.S. Appln. No. 09/206,040, BPAI Appeal No. 2002-0078.